Exhibit 5 510(k) Summary

K103182

Picture archiving and communications system / Model: Triana

JAN 14 2011

1. Company and Correspondent making the submission

1.1 Submitter and US Official Correspondent

Submitter: GENORAY Co., Ltd.
Address: #512, Byucksan Technopia, 434-6, Sangdaewon 1-dong, Jungwon-gu, Seongnam-city, Gyeonggi-do, 462-716 Korea
Telephone No.: +82-31-740-4100
Fax: +82-31-737-8025

1.2 Official Correspondent (U.S): Jae Kim - Business Manager

Correspondent: GENORAY America Inc.
Address: 1073 N. Batavia St. Orange, CA 92867, USA
Telephone No.: 714-289-8020
Fax: 714-453-9661
Email: jae@genoray.com

2. Establishment Registration Number

3005843418

3. Device Information

Proprietary / Trade Name:	Picture archiving and communications system / Model: Triana
Common / Usual Name:	Picture archiving and communications system
Classification Name:	System, Image Processing, Radiological
Product Code:	LLZ
Device Class:	Class II per regulation 21 CFR 892.2050

4. Equivalent Legally Marketed Device

Manufacturer:	CyberMed, Inc.
Device Name:	OnDemand3D
510(k) Number:	K070464 (Decision Date – March 16, 2007)
Classification:	System, Image Processing, Radiological: LLZ, Class II per regulation 21 CFR 892.2050

5. Description of the Device

Triana is a computer based dental imaging software which obtains medical images taken from CT, Cephalometric / Panoramic X-ray system & etc. and provides 3D visualization and 2D analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

Triana is designed to provide users easy and familiar user-interface. Also Triana makes it possible to manage medical images more easily and provides advanced tools for 2D and 3D analysis with rendering functions.

6. Indications for use

Triana is intended for use as a software package which obtains medical images from CT, Cephalometric / Panoramic X-ray system & etc., stores those and provides 3D visualization, 2D analysis, various MPR(Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

7. Safety and Effectiveness, comparison to Predicate

Triana, which is made by GENORAY Co., Ltd., is substantially equivalent to Ondemand3D of CyberMed, Inc. We selected the Ondemand3D as the predicate device already CE & FDA approved. Because of Ondemand3D and Triana are almost same in function & characteristic. Triana & OnDemand3D are intended for use as PACS software which obtains medical images from modality. And, these store images and provide 3D visualization and 2D analysis, various MPR functions for further rapid and precise diagnosis. The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

8. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 GENORAY Co., Ltd., concludes that the Picture archiving and communications system (Model: Triana) is safe and effective and substantially equivalent to the predicate device as described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GENORAY Co., Ltd.
% Mr. Jae Kim
Business Development Manager
1073 N. Batavia St.
ORANGE CA 92867

JAN 14 2011

Re: K103182
Trade/Device Name: Picture archiving and communications system (Models: Triana)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 15, 2010
Received: October 28, 2010

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit 4 Indications for use

510(k) number (if known): K103182

JAN 14 2011

Device Name: Picture archiving and communications system (Models: Triana)

Indications for Use:

Triana is intended for use as a software package which obtains medical images from CT, Cephalometric / Panoramic X-ray system & etc., stores those and provides 3D visualization, 2D analysis, various MPR(Multi-Planar Reconstruction) functions for further rapid and precise diagnosis.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103182